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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/424,048 02/24/00 VESEY

G 047763-5012

009629
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HM12/0525

EXAMINER

FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

05/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/424,048

Applicant(s)

VESEY ET AL.

Examiner

Ilesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20, and 22-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicant's amendment received February 26, 2001 (Paper No. 7) has been received and entered. Claim 21 was cancelled, consequently claims 1-20 and 22-23 are pending in the instant application.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Applicant's remarks directed to the rejection of claim 21 under 35 U.S.C. 112, second paragraph, which has been cancelled is considered moot and will not be further addressed.
2. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as vague and indefinite in the recitation of "sufficient time" is maintained.

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Applicant's assert that one skilled in the art would need at most to perform routine experimentation to elucidate what constitutes a "sufficient time" to generate the oocyst antigen preparation. Applicant's further assert that the specification teaches of a pretreatment step which includes boiling for 1 hour, thereby giving sufficient guidance as to how to prepare the oocyst antigen.

Applicant's arguments have been carefully considered but they are not deemed persuasive.

As was stated in a previous Office Action, one skilled in the art would be unable to determine the meets and bounds of such a limitation without a clear definition as to what constitutes a "sufficient time". Although the specification teaches of a pretreatment step which includes boiling for 1 hour, the claim does not recite this limitation.

Therefore, one of ordinary skill in the art would be forced into undue experimentation to practice the broadly claimed invention.

3. The rejection of claims 20-23 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicant's have indicated a willingness to perfect the deposit requirement upon an indication that all other claims are allowable. However, until the strain is deposited

and all rights irrevocable removed upon the granting of a patent, this rejection is maintained.

4. Claims 1-8 and 16-17 rejected under 35 U.S.C. 102 (b) as being anticipated by McDonald et al. (Parasitology 110:1995 pp. 259-98) is maintained.

The claims are drawn to a method of producing IgG antibodies to the surface of *Cryptosporidium* oocysts which are capable of eliciting an immune response in an animal.

Applicant's assert that the prior art is directed to methods of producing IgM and IgG antibodies and fails to disclose the methods of the claimed invention in particular, the "pretreatment of *Cryptosporidium* oocyst" to prepare a partially purified oocyst antigen preparation. Applicant's further assert that IgG antibody taught by McDonald et al. binds to the whole sporozoite rather than the oocyst surface.

Applicant's arguments have been carefully considered but they are not deemed persuasive.

McDonald et al. disclose a method of purifying *Cryptosporidium* oocysts including the pretreatment of oocysts (See Materials and Methods Section; especially parasites section). McDonald et al. further disclose that the oocysts were both isolated and purified. McDonald et al. further disclose that the IgG antibody was produced specifically against the oocysts wall (See Material and Methods Monoclonal Section). Applicant's have argued that "the antibody binds to the whole sporozoite" rather than to

the oocysts surface. However, McDonald et al. clearly states that "antibody 1B5 reacted solely with the oocysts wall " (See Results Section on page 261, line 5).

Regarding applicant's argument that McDonald et al. does not disclose that the IgG produced is of the IgG1 subclass. Applicant's arguments have been carefully considered but insufficient to overcome the rejection. Page 3, line 13, of the specification teaches that that the reagent hypochlorite can be used to prepare oocysts antigen to make IgG1 antibody. While it has been noted that McDonald et al. does not disclose the subclass of the IgG produced, the prior art uses acceptable methodology as taught by the applicant to prepare the oocysts antigen for making the IgG1 antibody.

5. Claims 9-15 and 18- 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al in view of Riggs et al. is maintained.

The claims are drawn to a method of producing isolated IgG1 antibodies which are reactive to the surface of *Cryptosporidium* oocysts.

Applicant's assert that the prior art does not teach or suggest a methodology that would result in the production of IgG1 antibodies. Applicant's further assert that the oocyst antigen preparation taught by Riggs et al. comprised oocysts walls, residual bodies and sporozoites.

Applicant's arguments have been carefully considered but they are not deemed persuasive.

Riggs et al. (Infection and Immunity 62 pp.1927-39 1994) clearly teach of

a method of oocyst isolation using the reagent hypochlorite (See Material and Methods Section; especially Oocyst Isolation Section in paragraph 2) and the immunization of animals using the purified oocyst preparation to make IgG antibodies. Riggs et al. further teach that oocysts were treated with peracetic acid to remove any residual contamination. For the same reasons set forth above, the IgG antibody claimed by the Applicant is being viewed as the same IgG taught in the prior art.

Regarding the applicant's argument that Riggs et al. does not disclose the separation of "at least part of the *Cryptosporidium* oocysts wall from internal sporozoites".

Riggs et al. teach of the immunization of three groups of animals. According to Riggs et al. one group was immunized with purified sonicated oocysts, the second group was immunized with purified sonicated sprozoites, and the third group was given an adjuvant only (See Material and Methods Section; especially Production and Processing of Colostrum). It is the Examiner's position that because Riggs et al. teach that one group of animals were immunized with purified oocysts it can be reasonably concluded that the oocyst preparation contained separation of "at least part of the *Cryptosporidium* oocysts wall from internal sporozoites". Therefore, the prior art meets all the limitations set forth in Claim 9.

Status of the Claims

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

May 23, 2001



MARK NAVARRO
PRIMARY EXAMINER